

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application:

Mark Bleyer, et al.

Serial No. 10/025,282

Filed December 19, 2001

RADIOPAQUE IMPLANTABLE  
COLLAGENOUS BIOMATERIAL  
DEVICE

)  
)  
) Before the Examiner  
) (Nguyen, D.)  
)  
) Group Art Unit  
) 1632  
)  
) Our Ref.: 3433-333  
)  
) September 28, 2005

I hereby certify that this correspondence is being deposited with the U. S. Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, Alexandria, VA 22313 on

September 28, 2005  
(Date of Deposit & Signature)

Kenneth A. Gandy

Name of Registered Representative

*Kenneth A. Gandy*  
Date of Signature

**INFORMATION DISCLOSURE STATEMENT**

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

**1. List of All Patents, Publications, U.S Applications or Other Information**

Pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, Applicant requests consideration of the references listed on the attached PTO/SB/08 form(s) (commonly referred to as a PTO-1449 form) and/or the additional information identified below.

**2. Enclosed Legible Copies**

a. A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed,

☒ i. except, a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior U.S. Patent Application Serial No. 09/444,881, filed November 22, 1999, from which the present application claims priority under 35 U.S.C. §120.

☐ ii. except, a copy is not provided for each cumulative reference and enclosed reference identified below:

☐ b. A copy of the specification and drawings for each cited unpublished U.S. application.

☐ c. A copy of a Search Report or Written Opinion from a foreign patent office is also enclosed.

☐ d. Consideration of the enclosed additional and/or below discussed information is requested.

### **3. Concise Explanation of Relevance for Non-English Language Information**

For each non-English language reference listed on the attached SB/08 form(s), reference is made to:

- ☐ 3a. an English language translation submitted herewith,
- ☐ 3b. foreign patent office Search Report (in the English language) submitted herewith,
- ☐ 3c. an English language translation of a foreign patent office Search Report submitted herewith,
- ☐ 3d. the concise explanation contained in the present application at page(s) \_\_\_\_\_,
- ☐ 3e. the concise explanation set forth in the attached English language abstract,
- ☐ 3f. a copy of a related patent publication (in the English language) submitted herewith,

Foreign Patent Document	Corresponding English Language Patent Document

- ☐ 3g. the following concise explanation:

### **4. Time for Filing**

- ☐ 4a. This Information Disclosure Statement is submitted:
  - ☐ i. for U.S. national applications or national stage PCT applications (not including CPAs and RCEs), within 3 months of filing or entry into national stage; **or**
  - ☐ ii. for U.S. national applications, national stage PCT applications, CPAs or RCEs, before the first Office Action on the merits,

**and thus no certification and/or fee is required.**

- ☐ 4b. This information Disclosure Statement is submitted after three months from the filing date and after the first Office Action on the merits, but prior to the mailing date of a final Office Action or Notice of Allowance, and thus:

- ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, **or**
- ☐ ii. a fee of **\$180.00** (set forth in 37 CFR §1.17(p)) is enclosed.

- ☒ 4c. This Information Disclosure Statement is submitted after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:

- ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, **and** a fee of **\$180.00** (set forth in 37 CFR §1.17(p)) is enclosed, **or**
- ☒ ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

- ☐ 4d. This Information Disclosure Statement is submitted after payment of the issue fee, and thus:
- i. a Petition to Withdraw from Issue pursuant to 37 CFR §1.313(c)(2) has been filed, and
  - ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

**5. Certification- Statement Under 37 CFR 1.97(e)**

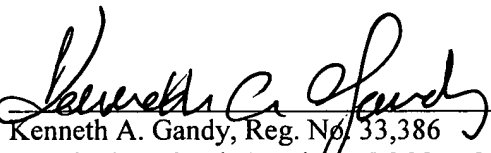
☐ 5a. It is hereby certified that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

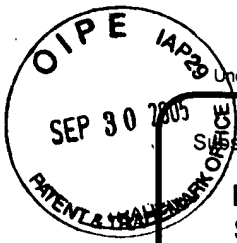
☐ 5b. A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.

☐ 5c. It is hereby certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b). It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted,

By   
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number 10/025,282

Filing Date December 19, 2001

First Named Inventor Bleyer, M.

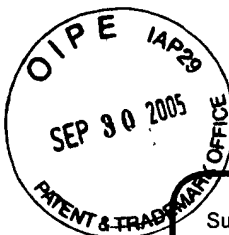
Group Art Unit 1632

Examiner Name Nguyen, D

Attorney Docket Number 3433-333

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (If known)			
		US-2,127,903	08/23/1938	Bowen, A.	
		US-3,562,820	02/16/1971	Braun, B.	
		US-4,795,741	01/03/1989	Leshchiner, et al.	
		US-4,902,508	02/20/1990	Badylak, et al.	
		US-4,956,178	09/11/1990	Badylak, et al.	
		US-5,139,505	08/18/1992	Palmieri, B.	
		US-5,141,747	05/25/1992	Scholz, M.	
		US-5,275,826	01/04/1994	Badylak, et al.	
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		US-5,372,821	12/13/1994	Badylak, et al.	
		US-5,460,962	10/24/1995	Kemp, P.	
		US-5,554,389	09/10/1996	Badylak, et al.	
		US-5,601,602	02/11/1997	Fowler, B.	
		US-5,609,629	03/11/1997	Fearnot, et al.	
		US-5,676,146	10/14/1997	Scarborough, N.	
		US-5,676,689	10/14/1997	Kensey, et al.	
		US-5,749,894	05/12/1998	Engelson, E.	
		US-5,788,625	08/04/1998	Plouhar, et al.	
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		US-6,048,362	04/11/2000	Berg, T.	
		US-6,096,070	08/01/2000	Ragheb, et al.	
		US-6,099,567	08/08/2000	Badylak, et al.	
		US-6,206,931	03/27/2001	Cook, et al.	
		US-6,358,284	03/19/2002	Fearnot, et al.	
		US-6,475,232	11/05/2002	Babbs, et al.	
		US 2002/0099448	07/25/2002	Hiles, et al.	
		US 2004/0078076	04/22/2004	Badylak, et al.	



#333159 3433-333 KAG WEMMH/SB/08A (4/03)

Approved for use through 10/31/2002. OMB 0651-0031

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Sheet 2 of 2

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Application Number 10/025,282

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First Named Inventor Bleyer, M.

Group Art Unit 1632

Examiner Name Nguyen, D

Attorney Docket Number 3433-333

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 94/26175	11/24/1994	Vitaphore Corporation		
		WO 95/22611	08/24/1995	The Regents of the University of Michigan		
		WO 96/24661	08/15/1996	Purdue Research Foundation, et al.		
		WO 96/25179	02/16/1996	Purdue Research Foundation		
		WO 96/32146	10/17/1996	Advanced Cytometrix, Inc.		
		WO 97/19643	06/05/1997	Endomatrix, Inc.		
		WO 98/22158	05/28/1998	Cook Biotech, Inc., et al.		
		WO 98/25545	06/18/1998	Cook Biotech, Inc.		
		WO 98/25636	06/18/1998	Purdue Research Foundation		
		WO 98/25637	06/18/1998	Purdue Research Foundation		
		WO 98/26291	06/18/1998	Purdue Research Foundation		
		WO 99/44538	09/10/1999	The Regents of the University of California, et al.		

Examiner  
SignatureDate  
Considered

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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#333172 3433-333 KAG WEMMH/SB/08B (4/03)

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STATEMENT BY APPLICANT**

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Sheet

1

of

1

**Complete if Known**

Application Number

10/025,282

Filing Date

December 19, 2001

First Named Inventor

Bleyer, M.

Group Art Unit

1632

Examiner Name

Nguyen, D

Attorney Docket Number

3433-333

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T <sup>2</sup>
		American National Standard, ANSI/AAMI 10993-1:1994. "Biological Evaluation of Medical Devices—Part 1: Guidance on Selection of Tests". Association for the Advancement of Medical Instrumentation. pp. 9-17.	
		BALDRY, M.G.C., et al., "Disinfection with Peroxygen", <i>Industrial Biocides</i> , 1988. pp. 91-116, K. Payne, editor. John Wiley and Sons, Inc., New York.	
		BLOCK, S. "Peroxygen Compounds", <i>Disinfection, Sterilization and Preservation</i> , 5 <sup>th</sup> Edition 2001. pp. 185-204. Lippincott Williams & Wilkins, Philadelphia, PA.	
		DENTON, F.W., "Chlorhexidine", <i>Disinfection, Sterilization and Preservation</i> , S. Block, editor, 5 <sup>th</sup> Edition 2001. pp. 321-336. Lippincott Williams & Wilkins, Philadelphia, PA.	
		HORAK, D., et al. "Hydrogels in Endovascular Embolization. III. Radiopaque Spherical Particles, Their Preparation and Properties". <i>Biomaterials</i> , March 1987. Vol. 2, No. 8. pp. 142-145. Butterworth-Heinemann In Association With The Biological Engineering Society, England.	
		KROPP, B.P., et al. "Experimental Assessment of Small Intestinal Submucosa as a Bladder Wall Substitute". <i>Urology</i> , 1995. Vol. 46, No. 3. pp. 396-400. Elsevier Science, United States.	

Examiner  
SignatureDate  
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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